Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HUMANA INC., **Plaintiff,** **v.** **CELGENE CORPORATION,** **Defendant.**	**Civil Action No.: 19-7532 (ES) (MAH)** **OPINION**

SALAS, DISTRICT JUDGE

Plaintiff Humana Inc. asserts various claims against Defendant Celgene Corporation under federal and state antitrust laws. The thrust of Humana's Complaint is that Celgene, a brand manufacturer, engaged in a series of conduct over the course of multiple years to exclude generic entry into the market for two brand drugs: Thalomid and Revlimid. Humana alleges that, as a result of Celgene's conduct, it has purchased those drugs at supracompetitive prices. Celgene moves to dismiss the Complaint. (D.E. No. 18). Having considered the parties' submissions, the Court decides this matter without oral argument. *See* Fed. R. Civ. P. 78(b); L. Civ. R. 78.1(b). As set forth below, the motion is DENIED.

I. BACKGROUND

In the mid-1900s, Thalidomide was a sleeping pill and anti-morning sickness pill for pregnant women. (D.E. No. 1 ("Compl.") ¶ 88). However, the pill caused life-threatening fetal deformities, leading to its world-wide ban. (*Id.*). That ban was in effect until July 16, 1998, when the federal Food & Drug Administration ("FDA") approved Celgene to reintroduce a version of it into the market as "Thalomid" for an alternative use—to treat erythema nodosum leprosum

("ENL"), a form of leprosy. (*Id.* ¶ 89). The FDA similarly approved Celgene to introduce Revlimid, a drug that shares similar chemical compounds as Thalomid, to treat transfusion dependent anemia. (*Id.* ¶ 92). Celgene holds dozens of patents protecting aspects of both drugs. (*Id.* ¶¶ 94–96).

Despite Celgene's patents, Humana claims that Celgene unlawfully monopolized the market in several ways. First, Humana claims that Celgene unlawfully denied generic drug manufacturers samples of both drugs to prevent them from developing generic versions. (*Id.* ¶¶ 99–101). Second, Humana claims that Celgene filed frivolous patent prosecutions in the U.S. Patent and Trademark Office ("USPTO"). (*Id.* ¶ 243). Third, Humana claims that Celgene filed sham litigations in court and a sham citizen petition with the FDA. (*Id.* ¶¶ 379–80). And fourth, Humana claims that Celgene may have entered into an illegal pay-for-delay settlement agreement with a generic manufacturer. (*Id.* ¶ 338). To understand the thrust of those claims, it is necessary outline six features of the Drug Price Competition and Patent Term Restoration Act of 1984—commonly known as the "Hatch-Waxman Act"—which governs brand and generic competition in the pharmaceutical drug industry.

A. The Hatch-Waxman Act

First, a drug manufacturer that wishes to market a new drug must submit a New Drug Application ("NDA") to the FDA. *See* 21 U.S.C. § 355(a). The NDA must include, *inter alia*, "full reports of investigations" into the safety and effectiveness of the new drug and "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug." § 355(b)(1). Before submitting an NDA, the applicant must therefore complete rigorous, comprehensive, and costly testing.

Second, due to the danger that some new drugs pose, the FDA may approve an NDA conditionally through a risk evaluation and mitigation strategies ("REMS") program. § 355-1. A REMS program can include a medication guide, a patient package insert, a communication plan to healthcare providers, or packaging and disposal requirements. § 355-1(e).

Third, a drug manufacturer may avoid the costly NDA process by submitting an Abbreviated New Drug Application ("ANDA"). § 355(j). The ANDA must show, *inter alia*, that the generic version is bioequivalent to the brand drug. § 355(j)(2)(A)(iv). In order to test for bioequivalence, the generic manufacturer ordinarily must have access to samples of the brand drug. (Compl. ¶¶ 36–37). To conduct such testing, ANDA applicants typically purchase samples from a drug wholesaler or distributor. (*Id.* ¶ 38). The purpose of this abbreviated process is to increase access to drugs by allowing lower-cost generic drugs to enter the market. *See Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

Fourth, the Hatch-Waxman Act further encourages generic entry by granting the first ANDA filer, if approved, a lucrative 180-day market exclusivity period. § 355(j)(5)(B)(iv)(I). The ANDA applicant can forfeit this exclusivity period in several ways, such as by withdrawing the ANDA, failing to obtain tentative approval within thirty months after the date it filed the ANDA, or entering into a pay-for-delay agreement that violates federal antitrust laws (as determined by a final decision of the Federal Trade Commission or a court). § 355(j)(5)(D)(i)(II), (IV) & (V). If an initial ANDA applicant forfeits this exclusivity period, a subsequent ANDA applicant is not eligible for the 180-day exclusivity period. § 355(j)(5)(D)(iii)(II).

Fifth, the Hatch-Waxman Act sets out a process for resolving patent disputes that inevitably arise from the ANDA process. Indeed, NDAs are for *new* drugs, and the ANDA application must show bioequivalence. The Hatch-Waxman Act requires an ANDA applicant to certify that the

generic version will not infringe the brand drug's associated patents. § 355(j)(2)(A)(vii)(I)–(IV). The ANDA applicant can make that assurance in several ways, one of which is by filing a Paragraph IV certification stating that the brand drug's associated patents are "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." § 355(j)(2)(A)(vii)(IV). However, a Paragraph IV certification is considered an "act of infringement" under federal law. 35 U.S.C. § 271(e)(2)(A). Thus, a Paragraph IV certification often provokes litigation from the NDA holder who seeks to protect its patents on the brand drug. *See Caraco Pharm. Lab'ys*, 566 U.S. at 407 ("Filing a paragraph IV certification means provoking litigation."). If the NDA holder files suit within the applicable time frame, the FDA must forego approval of the ANDA while the parties litigate the patent issue—usually for a thirty-month period. 21 U.S.C. § 355(j)(5)(B)(iii). If a court decides the issue within thirty months, the FDA will follow the court's determination; if the case is not resolved within thirty months, then the FDA may move forward in deciding the ANDA. *Id.* "Accordingly, the paragraph IV process is likely to keep the generic drug off the market for a lengthy period, but may eventually enable the generic company to market its drug for all approved uses." *Caraco Pharm. Lab'ys*, 566 U.S. at 407–08.

Sixth, an interested person may submit a "citizen petition" to the Commissioner of the FDA requesting the Commissioner to take some action—such as staying the effective date of any administrative action—with respect to an ANDA. § 355(q)(1)(A); *see also* 21 C.F.R. §§ 10.30 & 10.35. The FDA may deny the citizen petition if the petition's sole purpose is to delay ANDA approval or if the petition does not "raise valid scientific or regulatory issues." 21 U.S.C. § 355(q)(1)(E). That said, frivolously filed citizen petitions effectively delay ANDAs because such petitions exhaust the FDA's limited resources to investigate the underlying claims. (Compl. ¶ 82).

B. Factual Allegations

As noted above, Humana claims that Celgene engaged in a series of actions to prevent or delay generic entry into the market for Thalomid and Revlimid by (i) denying generic drug manufacturers samples needed to test for bioequivalence and thereby file an ANDA, (ii) filing frivolous patent prosecutions with the USPTO, (iii) filing sham litigations in federal court and a sham citizen petition with the FDA, and (iv) entering into an illegal pay-for-delay settlement agreement with a generic manufacturer to end an ANDA litigation.

Samples: Central to Humana's refusal-to-deal allegations is that the FDA approved Thalomid and Revlimid on the condition that both drugs would follow their own REMS programs. (Compl. ¶¶ 89–90 & 93). Thalomid's program is called the "System for Thalidomide Education and Prescribing Safety" ("S.T.E.P.S."). (*Id.* ¶ 89). Revlimid's program is called RevAssist. (*Id.* ¶ 93). Under S.T.E.P.S. and RevAssist, generic manufacturers could purchase brand samples only from Celgene directly because the programs prevented their purchase through normal wholesale distribution channels. (*Id.* ¶ 106). Consequently, Celgene effectively controlled the sale of Thalomid and Revlimid.

Humana alleges that Celgene refused to sell samples of those drugs to several generic drug manufacturers—specifically, to Mylan Pharmaceuticals Inc.; Lannett Company; Exela Pharmsci, Inc.; Dr. Reddy's Laboratories; Watson Laboratories, Inc.; Teva Pharmaceuticals USA; and Sandoz Inc. (*Id.* ¶ 100). Celgene allegedly did so by, among other things, citing the drugs' respective REMS programs and other purported safety concerns, stating that it was under no obligation to provide samples, stating its denial in conclusory fashion, and issuing information requests for reconsideration. (*E.g.*, Compl. ¶¶ 137, 173, 179, 198, 201, 205, 210 & 216). In an attempt to combat Celgene's reliance on REMS as a basis for refusal, Mylan, Lannett, Exela, and

Sandoz received FDA approval to purchase the samples even though FDA approval was not necessary for a competitor to purchase samples to test for bioequivalence. (Compl. ¶¶ 103–04, 144, 170, 177 & 215). After several years of delay, Lannett eventually procured samples of Thalomid and filed an ANDA but was thereafter sued for patent infringement. (*Id.* ¶ 195). It also appears that Dr. Reddy's was able to obtain samples of Revlimid—the source not alleged—because it eventually filed an ANDA for a generic form of Revlimid. (*Id.* ¶ 202). But just as with Lannett, Celgene sued Dr. Reddy's for patent infringement. (*Id.*). No other competitor, it appears, purchased samples of Thalomid or Revlimid from Celgene. (*Id.* ¶¶ 156, 173, 206, 212 & 218).

Similarly, Humana alleges that Celgene entered into an exclusive supply agreement with Seratec S.A.R.L. to prevent Barr Laboratories from obtaining "thalidomide['s]" active pharmaceutical ingredient. (*Id.* ¶¶ 219–22). Barr eventually obtained "Thalomid samples" from another source, tested its generic versions for bioequivalence, and later filed an ANDA. (*Id.* ¶ 225 & n.69). In response, Celgene sued Barr for patent infringement. (*Id.* ¶ 226).

With respect to timing, the Complaint alleges that Mylan requested samples as early as December 22, 2003. (*Id.* ¶ 108). The Complaint further alleges that Celgene denied samples to Mylan as late as March 20, 2014, causing Mylan to file suit on April 3, 2014. (*Id.* ¶ 142). It appears that the remaining requests for samples and corresponding denials occurred sometime between October 2003 and April 2014. (*Id.* ¶¶ 172–73, 195, 198, 205, 210 & 213). The allegations concerning Barr occurred between 2004 and 2006. (*Id.* ¶¶ 220 & 225).

Patent Prosecution: Humana claims that Celgene created a near-impenetrable "patent fortress" by prosecuting invalid and unenforceable patents related to Thalomid and Revlimid. (*Id.* ¶ 95). Humana takes issue with three categories of Celgene's patents: composition patents, polymorphic patents, and distribution patents. Celgene's composition patents are invalid,

according to Humana, on grounds of prior art and obviousness and on the basis that Celgene failed to disclose material information to the USPTO when filing for those patents. (*Id.* ¶¶ 244–246). With respect to the polymorph patents, Humana claims that Celgene obtained two patents on the polymorphic form of lenalidomide even though polymorphs are "generally not separately patentable." (*Id.* ¶¶ 247–48). Moreover, the polymorphic patents, Humana goes on, are invalid as redundant and obvious, for deficiencies in the written patent description, and for the same reasons the composition patent related to Revlimid is invalid. (*Id.* ¶¶ 247–51). The polymorphic patents "have the latest expiration dates of any patents associated with Thalomid or Revlimid"—they expire in 2024 and 2027—and therefore "have been key patents cited in repeated attempts by Celgene to block generic competitors from the market." (*Id.* ¶ 248). Finally, Humana levels similar allegations, though in far greater detail, concerning several of Celgene's distribution-method patents and one of Celgene's dosing patents. (*Id.* ¶¶ 252–321).

With respect to the timeline of the alleged unlawful patent prosecutions, the earliest-filed patent was the composition patent for Revlimid, which was filed on July 24, 1996, and later issued on June 3, 1997. (*Id.* ¶ 96 (table of patents)). The latest-filed patent concerned a method for delivering Thalomid and Revlimid, which was filed on December 13, 2010, and issued on November 20, 2012. (*Id.*).[1]

Sham Litigations and Citizen Petitions: Humana alleges that Celgene brought sham infringement claims against companies that eventually filed ANDAs[2]—namely, against Barr in 2007; against Natco Pharma Limited, Watson, and Arrow International Ltd in 2010; against Lannett in 2015; against Dr. Reddy's in 2016; against Zydus Pharmaceuticals in 2017; against

[1] There are "younger" patents, but Humana did not include those patents in its allegations concerning unlawful patent prosecutions in the USPTO.

[2] As explained above, the Complaint does not clearly disclose how these competitors obtained the samples necessary to file ANDAs.

CIPLA Ltd. in 2017; against Alvogen, Inc. and Lotus Pharmaceuticals in 2018; and against Sun Pharmaceuticals in 2018. (*Id.* ¶¶ 326, 340, 348, 359, 362, 366, 370 & 374). Celgene also allegedly filed a frivolous citizen petition urging the FDA to block Barr's ANDA on September 20, 2007. (*Id.* ¶¶ 326 & 329).

As of the filing of the Complaint, the cases involving Barr; Natco, Watson, and Arrow; and Lannett had settled (*id.* ¶¶ 334, 342 & 357), and the remaining cases were pending (*id.* ¶¶ 361, 364, 368, 372 & 376). However, having independently reviewed the respective dockets, the Court understands that the then-pending cases have ended in consent judgments. In addition, the FDA denied the citizen petition related to Barr's ANDA on September 30, 2014. (*Id.* ¶ 332).

Humana claims the above lawsuits were frivolous for largely the same reasons that Celgene's patent prosecutions in the USPTO were frivolous—because Celgene was knowingly prosecuting clearly invalid patents in order to delay generic entry into the market. (*Id.* ¶ 324).

Pay for Delay: There is only one allegation concerning pay-for-delay in the Complaint. Humana alleges that Celgene and Barr entered into a "confidential settlement which may have contained illegal pay-for-delay provisions." (*Id.* ¶ 338).

* * *

Humana alleges that, "[b]ut for Celgene's anticompetitive scheme, generic Thalomid would have been brought to market as early as 2006," and "generic Revlimid would have entered the market as early as 2009 and 2010." (*Id.* ¶¶ 379–80). As a result, Humana claims that it has "paid substantial sums to purchase Thalomid and Revlimid" at "artificially high, supracompetitive prices." (*Id.* ¶ 403).

C. Procedural History

On March 1, 2019, Humana filed suit against Celgene, alleging violations of Section 2 of the Sherman Act, 15 U.S.C. § 2 (first claim for relief); monopolization and monopolistic scheme under state law (second claim for relief); attempted monopolization under various state laws (third claim for relief); unfair and deceptive trade practices under state law (fourth claim for relief); and unjust enrichment under state law (fifth claim for relief). (*Id.* ¶¶ 408–40). In addition to damages, Humana seeks declaratory and injunctive relief. (*Id.* ¶¶ 450–55). Thereafter, Celgene moved to dismiss the Complaint.

II. LEGAL STANDARD

In assessing whether a complaint states a cause of action sufficient to survive dismissal under Federal Rule of Civil Procedure 12(b)(6), the Court accepts "all well-pleaded allegations as true and draw[s] all reasonable inferences in favor of the plaintiff." *City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp.*, 908 F.3d 872, 878 (3d Cir. 2018). "[T]hreadbare recitals of the elements of a cause of action, legal conclusions, and conclusory statements" are all disregarded. *Id.* at 878–79 (quoting *James v. City of Wilkes-Barre*, 700 F.3d 675, 681 (3d Cir. 2012)). The complaint must "contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face," and a claim is facially plausible when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Zuber v. Boscov's*, 871 F.3d 255, 258 (3d Cir. 2017) (first quoting *Santiago v. Warminster Twp.*, 629 F.3d 121, 128 (3d Cir. 2010); and then quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

Although Rule 12 does not explicitly permit a defendant to raise a time-bar defense on a motion to dismiss, "this Circuit . . . permits a limitations defense to be raised by a motion under

Rule 12(b)(6), but only if 'the time alleged in the statement of a claim shows that the cause of action has not been brought within the statute of limitations.'" *Robinson v. Johnson*, 313 F.3d 128, 135 (3d Cir. 2002) (quoting *Hanna v. U.S. Veterans' Admin. Hosp.*, 514 F.2d 1092, 1094 (3d Cir. 1975)). "If the bar is not apparent on the face of the complaint, then it may not afford the basis for a dismissal of the complaint under Rule 12(b)(6)." *Id.* (quoting *Bethel v. Jendoco Constr. Corp.*, 570 F.2d 1168, 1174 (3d Cir. 1978)).

III. DISCUSSION

Celgene argues that many of the claims of monopolization in the Complaint are time barred and that the Complaint otherwise fails to state a claim on which relief can be granted.

A. Statute of Limitations

The Clayton Act imposes a four-year statute of limitations for damages actions under the Sherman Act. *See* 15 U.S.C. § 15b. While Humana filed suit in March 2019, the parties entered a nine-month tolling agreement, which means Humana constructively filed the Complaint in June 2018. (Mov. Br. at 11 n.6; D.E. No. 20 ("Opp. Br.") at 8 n.11). Thus, to comply with the four-year limitations period, Humana's claim must have accrued in or after June 2014.

Generally, a cause of action accrues "when a defendant commits an act that injures a plaintiff's business." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971). Celgene argues that Humana's causes of action accrued as early as 2006 and 2009—when Humana alleges it first suffered an injury—because that was when generic versions of Thalomid and Revlimid "would have," according to Humana, entered the market but for Celgene's unlawful conduct. (Mov. Br. at 14 (quoting Compl. ¶¶ 379–80)). In response, Humana invokes the continuing violations doctrine, which holds that a new cause of action accrues for each overt act committed within the four-year limitations period. (Opp. Br. at 8–10). According to Humana,

each sale of Thalomid and Revlimid at monopolistic prices triggered a new cause of action—because a direct purchaser, such as itself, is injured only when it purchases a good or service at a supracompetitive price. (*Id.* at 10–11 & nn.20–21). The Court agrees with Humana.

The Court's discussion begins with *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 392 U.S. 481 (1968), *West Penn Allegheny Health System, Inc. v. UPMC*, 627 F.3d 85 (3d Cir. 2010), *Zenith Radio*, 401 U.S. 321, and *Klehr v. A.O. Smith Corp.*, 521 U.S. 179 (1997). After, the Court will address out-of-circuit precedent and Celgene's arguments more particularly.

i. Supreme Court and Third Circuit Precedent

In *Hanover Shoe*, 392 U.S. 481, the Supreme Court recognized the so-called continuing violations doctrine. There, the defendant had refused to sell shoe machinery to the plaintiff pursuant to its lease-only policy. *Id.* at 483–84. The plaintiff, like Humana, sued under Section 2 of the Sherman Act, which generally prohibits attempts and conspiracies to monopolize a market. *Id.* at 483. But the plaintiff filed suit in 1955—challenging a policy first instituted in 1912. *Id.* at 502 n.15. However, the Supreme Court rejected the defendant's argument that the four-year statute of limitations precluded suit, explaining that it was "not dealing with a violation which, if it occurs at all, must occur within some specific and limited time span." *Id.* Instead, defendant's conduct "constituted a continuing violation of the Sherman Act . . . which inflicted continuing and accumulating harm on [the plaintiff]." *Id.*

And the Supreme Court so held, the Third Circuit explained in *West Penn*, 627 F.3d 85, "even though the injurious acts that took place within the limitations period—*i.e.*, instances in which the machinery company persisted in its refusal to offer its equipment for sale—were simply manifestations of the lease-only policy, which had been established in 1912, well before the start of the limitations period." *Id.* at 107. In contrast to other courts of appeals, the Third Circuit

announced that, per the continuing violations doctrine, a plaintiff's suit may be timely even if "the acts that occurred within the limitations period [a]re reaffirmations of decisions originally made outside the limitations period." *Id.*

In *Zenith Radio*, 401 U.S. 321, the Supreme Court expounded on the doctrine. There, Zenith Radio claimed that Hazeltine Research, Inc. violated the Sherman Act by conspiring with others to exclude Zenith Radio and other American manufacturers from participating in patent pools in foreign markets. *Id.* at 323. The Supreme Court addressed the question whether Zenith Radio could recover all damages that it suffered between 1959 and 1963, even though some portion of damages were proximately caused by conduct that occurred more than four years before Zenith Radio had filed its claim. *Id.* at 333. The Court answered that question in the affirmative. *Id.* The Court acknowledged that, generally, "a cause of action accrues . . . when a defendant commits an act that injures a plaintiff's business." *Id.* at 338. The Court went on that, "[i]n the context of a continuing conspiracy to violate the antitrust laws, such as the conspiracy in the instant case, this has usually been understood to mean that each time a plaintiff is injured by an act of the defendants[,] a cause of action accrues to him to recover the damages caused by that act and that, as to those damages, the statute of limitations runs from the commission of the act." *Id.* Thus, "if a plaintiff feels the adverse impact of an antitrust conspiracy on a particular date, a cause of action immediately accrues to him to recover all damages incurred by that date and all provable damages that will flow in the future from the acts of the conspirators on that date." *Id.* at 339.

Finally, in *Klehr*, 521 U.S. 179, the Supreme Court explained that the "Clayton Act . . . provides that, in the case of a 'continuing violation,' say, a price-fixing conspiracy that brings about a series of unlawfully high priced sales over a period of years, 'each overt act that is part of the violation and that injures the plaintiff,' *e.g.,* each sale to the plaintiff, 'starts the statutory period

running again, regardless of the plaintiff's knowledge of the alleged illegality at much earlier times.'" *Id.* at 189 (quoting 2 P. Areeda & H. Hovenkamp, Antitrust Law ¶ 338b, p. 145 (rev. ed. 1995); and then citing, *inter alia*, *Zenith Radio*, 401 U.S. at 338; *Hanover Shoe*, 392 U.S. at 502 n.15).

Thus, based on *Hanover Shoe*, *West Penn*, *Zenith Radio*, and *Klehr*, an antitrust plaintiff may sue for injuries that are merely manifestations or reaffirmations of acts that occurred well before the start of the limitations period—especially if the plaintiff suffers an injury on a particular date. Moreover, as reflected in the case law, a continuing violation with respect to supracompetitive prices *may* occur for *each sale* of the unlawfully high-priced item.

ii. Second and Fourth Circuit Precedent

It is not exactly clear how far the continuing violations doctrine extends with respect to supracompetitive prices. In the context of this case, the Second and Fourth Circuits are instructive. *See Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979); *Mayor of Baltimore v. Actelion Pharmaceuticals Ltd.*, 995 F.3d 123 (4th Cir. 2021). Both circuits hold that a direct purchaser—like Humana—as opposed to a competitor, may sue for overcharges caused by anticompetitive conduct that the monopolist committed before the four-year limitations period.

In *Berkey Photo*, 603 F.2d 263, Berkey Photo, like Humana, was a direct purchaser, but of photofinishing equipment and supplies from Eastman Kodak. *Id.* at 267. Like Humana, Berkey Photo sued Eastman Kodak under Section 2 of the Sherman Act for leveraging its monopoly in the camera and film markets to gain an unfair competitive advantage in the market for photofinishing equipment and supplies. *Id.* at 267–68, 275. Such conduct, Berkey Photo claimed, caused it to pay supracompetitive prices, just as Humana claims here. *Id.* at 267–68.

The Second Circuit addressed the following question: "If an overcharge paid during the

limitations period was caused by the defendant's monopoly power, may a plaintiff satisfy the conduct element of the [Section] 2 offense by proving anticompetitive actions that occurred more than four years prior to the commencement of suit?" *Id.* at 294. Answering that question in the affirmative, the Second Circuit reasoned that a direct "purchaser's claim cannot accrue until it actually pays the overcharge." *Id.* at 295. That is in contrast to a competitor's claim. "Although the business of a monopolist's rival may be injured at the time the anticompetitive conduct occurs," the Second Circuit explained, "a purchaser, by contrast, is not harmed until the monopolist actually exercises its illicit power to extract an excessive price." *Id.*

In addition to the general accrual rule, the Second Circuit also discussed the correlative speculative-damages doctrine. "[E]ven if injury and a cause of action have accrued as of a certain date, further damages that might arise from the conduct sued on are unrecoverable if the fact of their accrual is speculative or their amount and nature unprovable." *Id.* (quoting *Zenith Radio*, 401 U.S. at 339). And "[p]lainly, at the time a monopolist commits anticompetitive conduct it is entirely speculative how much damage that action will cause its purchasers in the future." *Id.*

However, the Second Circuit did not limit its holding to the accrual rule or the speculative-damages doctrine. "[I]n this setting," the Second Circuit explained, "as in 'the context of a continuing conspiracy to violate the antitrust laws, . . . each time a plaintiff is injured by an act of the defendants a cause of action accrues to him to recover the damages caused by that act.'" *Id.* (quoting *Zenith Radio*, 401 U.S. at 338). Indeed, "[s]o long as a monopolist continues to use the power it has gained illicitly to overcharge its customers, it has no claim on the repose that a statute of limitations is intended to provide." *Id.* Thus, a continuing violation occurs with respect to a direct purchaser each time the direct purchaser pays an unlawful supracompetitive price because, in contrast to a competitor, a direct purchaser is injured only at the time of sale. *Id.* at 296 ("We

hold, therefore, that a purchaser suing a monopolist for overcharges paid within the previous four years may satisfy the conduct prerequisite to recovery by pointing to anticompetitive actions taken before the limitations period.").[3]

A holding to the contrary, the Second Circuit went on, would mean that a purchaser could never recover future damages that falls outside the four-year period after a monopolist's anticompetitive conduct. *Id.* The Second Circuit further reasoned that its holding comported with fundamental fairness. On the one hand, a monopolist should not reap the benefits of unlawful conduct. *Id.* And on the other hand, its holding would not permit a direct purchaser to file suit long after the monopolist engaged in the underlying anticompetitive conduct, because the purchaser's allegations and evidence could be too remote to establish causation. *Id.* ("It should not be inferred that this ruling grants antitrust plaintiffs a license to embark on a search for Ichthyosauria—that is, on a time-warped fishing expedition.").

In accord with the Second Circuit is the Fourth Circuit's holding in *Actelion*, 995 F.3d 123. That decision is especially persuasive because it dealt with similar factual allegations regarding a drug manufacturer's supracompetitive pricing of a brand drug. There, purchasers of a brand drug—like Humana—sued the brand manufacturer, claiming that it engaged in a multi-year scheme to block at least four generic manufacturers from filing ANDAs with the intent to maintain its patent monopoly power beyond the patent's expiration date. *Id.* at 126–28. Much as Humana alleges, these direct purchasers claimed that the brand manufacturer blocked a generic drug from

[3] *See also Rite Aid Corp. v. Am. Exp. Travel Related Servs. Co.*, 708 F. Supp. 2d 257, 265 (E.D.N.Y. 2010) ("Under *Berkey*'s purchaser rule, [p]laintiffs' section two overcharge claims accrued when they paid Amex a supracompetitive merchant discount fee. The statute of limitations in this context only bars [p]laintiffs' claims based on overcharges outside of the limitations period—*i.e.* overcharges paid more than four years before filing suit."); *Molecular Diagnostics Lab'ys v. Hoffmann-La Roche Inc.*, 402 F. Supp. 2d 276, 286 (D.D.C. 2005) ("That MDL is litigating this action as a purchaser, not a competitor, is a critical distinction. Indeed, the Second Circuit has clarified the implications of this difference in the plaintiff's market position *vis a vis* an argument that a continuing violation has occurred.").

entering the market by (i) refusing to sell generic manufacturers samples of the brand drug, (ii) suing generic manufacturers for declaratory relief when the generic manufacturers threatened to sue the brand manufacturer under the antitrust laws, and (iii) settling with the generic manufacturers, the terms of which were not publicly disclosed. *Id.* The last overt act to exclude generic entry—*i.e.*, the settlement—occurred in February 2014. *Id.* at 128. The purchasers claimed that this scheme caused them to pay supracompetitive prices as early as November 2015, because that was when the brand drug's patent expired and when generic versions could have entered the market. *Id.* at 127–28.

Just as Celgene urges the Court to do here, the district court in *Actelion* dismissed the purchasers' claims under Sections 2 and 4 as untimely because the purchasers brought their claims more than four years after February 2014—which is when the scheme ended. *Id.* at 128. The district court explained that when a plaintiff asserts a continual refusal to deal, the cause of action accrues from the last overt act causing the plaintiff's injury. *Id.*

The Fourth Circuit reversed. First, the Fourth Circuit explained that a cause of action under Sections 2 and 4 of the Sherman Act accrues when the plaintiff is injured, and that a direct purchaser—as opposed to a competitor—is injured when a monopolist charges a supracompetitive price. *Id.* at 129–30. Thus, the earliest the purchasers could have brought suit was in November 2015, when the patents expired, which was within the four-year statute of limitations. *Id.* at 130. Second, the Fourth Circuit explained that the purchasers could not have brought suit any sooner, even though they were aware of the brand manufacturer's anticompetitive conduct, because their claims for damages would have been too speculative. *Id.* at 130–31. Third, and most relevant to the present case, the Fourth Circuit held that, "[q]uite apart from application of the standard antitrust accrual rule and the correlative speculative-damages doctrine, which render the plaintiffs'

action timely, the continuing-violation doctrine would also entitle the plaintiffs to recover damages *for each supracompetitive sale that* [*the brand manufacturer*] *made after November 2015*." *Id.* at 131 (emphasis added). "[E]ach time that [the brand manufacturer] sold [the brand drug] at a supracompetitive price after its patent expired, it illegally exercised monopoly power—*i.e.*, willfully maintained monopoly power—thus committing an overt act that caused injury and violated the antitrust laws." *Id.* (citing *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966)). "Accordingly, a new limitations period began to run from each such sale." *Id.*

Crucially, and it bears emphasis, the purchasers were not *per se* bringing a refusal-to-deal claim. Indeed, unlike with its competitors, the brand manufacturer did not refuse to deal with, *i.e.*, sell samples to, the purchasers. *Id.* at 131–32. Instead, the purchasers claimed, much like Humana does here, that the brand manufacturer engaged in an illegal scheme to delay generic entry into the market so that it could thereafter charge supracompetitive prices. *Id.* at 132. That claim, the Fourth Circuit reasoned, was functionally closer to a claim alleging pay-for-delay than it was to a claim alleging refusal-to-deal. *Id.* And "[v]irtually every court faced with similar allegations [of unlawful delay] has held, citing the continuing-violation doctrine, 'that a new cause of action accrues to purchasers upon each overpriced sale of the drug.'" *Id.* (quoting Malla Pollack, 6 *Callmann on Unfair Competition, Trademarks, and Monopolization* § 23:32 (4th ed. 2019) (collecting cases)).

The Court finds the Second Circuit's and the Fourth Circuit's views persuasive and in line with Supreme Court and Third Circuit precedent. As explained above, Supreme Court and Third Circuit precedent permit an antitrust plaintiff to sue for injuries that are merely manifestations or reaffirmations of overt acts that occurred well before the start of the limitations period—especially if the plaintiff suffers an injury on a particular date. And a continuing violation with respect to

supracompetitive prices may occur for each sale of the unlawfully high-priced item. If there is any limiting principle on the continuing violations doctrine vis-à-vis supracompetitive prices, it does not apply, per Second and Fourth Circuit precedent, when a direct purchaser sues for unlawful delay.

Here, Humana is a direct purchaser and suffers an injury as a result of Celgene's anticompetitive behavior *only* when it purchases Thalomid and Revlimid at a supracompetitive price, *not* when Celgene engages in the unlawful conduct. While the illegal price was allegedly established as early as 2006 and 2009, Humana alleges that it continues to pay supracompetitive prices today as a result of Celgene's ongoing scheme to monopolize and control the market. Humana alleges that it suffers a new injury each time it purchases Thalomid and Revlimid at a supracompetitive price.

Moreover, Humana's theory, like the theory in *Actelion*, concerns a multi-year, multi-part scheme to delay generic entry into the market. As alleged, Celgene delayed generic entry by refusing to sell samples to competitors and by later frivolously suing competitors for patent infringement once they filed an ANDA. All the lawsuits ended in confidential settlement agreements. The allegations span over several years and concern several different competitors. As of the Complaint's filing, no generic version of Thalomid or Revlimid had entered the market, even though, accepting the allegations as true, such versions should have entered the market more than ten years ago. These facts are akin to pay-for-delay, which courts overwhelmingly have found support application of the continuing violations doctrine to each supracompetitive sale.

Therefore, Humana may sue for damages that it suffered from June 2014 and beyond.

iii. Celgene's Counterarguments

Celgene raises several arguments to the contrary. None is persuasive.

First, Celgene argues that *Klehr*'s discussion of unlawfully high-priced sales is limited to cases involving price-fixing conspiracies, because *Klehr*'s hypothetical was about a price-fixing conspiracy. (D.E. No. 21 ("Reply") at 2–3). *Klehr* does not apply, Celgene goes on, to cases involving allegations of unilateral anticompetitive conduct such as this one. (*Id.* at 3). That is so, Celgene argues, because (i) the continuing violations doctrine requires an overt act that is "***part of the violation***" and (ii) Section 2 of the Sherman Act does not prohibit merely "possessing monopoly power and charging monopoly prices." (*Id.* at 2 (first quoting *Klehr*, 521 U.S. at 189; and then quoting *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 447–48 (2009)) (emphasis added by Celgene)).

This argument has some logical appeal but is not persuasive for several reasons. For starters, *Klehr* did not explicitly limit itself to price-fixing conspiracies, even if the hypothetical involved a price-fixing conspiracy. Moreover, essential to the Court's holding here is that Humana is a direct purchaser alleging unlawful delay. As a direct purchaser, Humana suffers an injury and has a cause of action when it actually pays a supracompetitive price, not when Celgene engages in conduct that unlawfully hinders or delays a competitor from entering the market. Much like in *Hanover Shoe*, a case also brought under Section 2, the Court here is "not dealing with a violation which, if it occurs at all, must occur within some specific and limited time span" but instead "with conduct which constituted a continuing violation of the Sherman Act and which inflicted continuing and accumulating harm on [the plaintiff]." 392 U.S. at 502 n.15.

Second, and similarly, Celgene argues that the pay-for-delay cases, which were relied upon by the Fourth Circuit, are distinguishable because those cases involve "a specific form of conspiracy to monopolize in which potential competitors agree to share the monopolists' profits in exchange for one competitor remaining out of the market." (Reply at 5). "In that context," says

Celgene, "the charging of supracompetitive prices ***is an overt act in furtherance of the conspiracy not to compete*** . . . ." (*Id.* (emphasis added by Celgene)). As the Court understands it, Celgene appears to suggest that pay-for-delay is different because pay-for-delay involves a profit-sharing agreement and therefore price is integral to the antitrust violation. Meanwhile, price is not an aspect or an element of the antitrust violation in this case.

But Celgene does not accurately describe all pay-for-delay agreements. Pay-for-delay, which often arises in the pharmaceutical patent context, is a "reverse payment" in which "a patentee pays an alleged infringer to end a lawsuit." *F.T.C. v. AbbVie Inc*, 976 F.3d 327, 351 (3d Cir. 2020).

> A typical reverse payment happens this way: "Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars."

Id. (quoting *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 140 (2013)). Such agreements may be unlawful—not because there is an agreement to fix price, or because there is a profit-sharing arrangement between two competitors—but because two competitors agree not to compete and thereby unlawfully and unreasonably allocate market power. *Id.* at 351–52. Under these agreements, the prospective generic manufacturer does not always share the monopoly profits—because it does not always or necessarily obtain a portion of the brand manufacturer's later-earned profits. *Id.* at 353–55 (describing various reverse payments that did not involve a profit-sharing arrangement). Indeed, reverse payments may be anticompetitive "regardless of their form." *Id.* at 356.

Following a reverse-payment scheme, the monopolist may (and usually will) charge supracompetitive prices. But those prices are a consequence of the agreement not to compete.

Similarly, Celgene allegedly charged supracompetitive prices, not because doing so was necessary to its scheme to delay generic entry, but as a consequence of its conduct. Thus, if price is *part* of a pay-for-delay conspiracy, then it is only so in the same way that price is *part* of this Section 2 case. In both situations price not a necessary aspect of the violation, and in both situations supracompetitive prices flow as a consequence of both the violation and a voluntary decision of the monopolist. Accordingly, in both contexts, the "ongoing sales . . . at a supracompetitive price constitute a continuing violation." *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 746 (E.D. Pa. 2014). "In other words, the continuing act of charging higher prices is the continuing violation, and a plaintiff is not limited by the initial acts of predatory pricing by the defendant." *In re Relafen Antitrust Litig.*, 286 F. Supp. 2d 56, 62 (D. Mass. 2003) (distinguishing cases brought by purchasers and competitors). The Fourth Circuit's reliance on pay-for-delay cases is therefore persuasive.[4]

Third, Celgene relies on *Z Technologies Corp. v. Lubrizol Corp.*, 753 F.3d 594 (6th Cir. 2014), and *US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43 (2d Cir. 2019). (D.E. No. 53 at 2 n.1). But those cases are inapposite.

In *Z Technologies*, 753 F.3d 594, the Sixth Circuit held that price increases, even when paid by a direct purchaser, are not continuing violations because "the Sixth Circuit has repeatedly rejected invocations of the continuing-violations defense that are mere reaffirmations of a previous act." *Id.* at 600. However, the central takeaway from the Third Circuit's binding decision in *West Penn* is that a plaintiff's suit is timely even if "the acts that occurred within the limitations period

[4] Humana raises a pay-for-delay allegation with respect to Celgene and Barr, claiming that a confidential agreement between the two "may have contained illegal pay-for-delay provisions." (Compl. ¶ 338). However, that aspect of the Complaint is so insufficiently pled that the Court does not rely on it as support for the statute-of-limitations analysis. That said, the Court finds the pay-for-delay cases sufficiently analogous to Humana's other allegations against Celgene, and accordingly, reliance on those cases for the statute-of-limitations analysis is appropriate.

[a]re reaffirmations of decisions originally made outside the limitations period." 627 F.3d at 107.

In *US Airways*, 938 F.3d 43, the Second Circuit held that a defendant does not commit an overt act each time a plaintiff pays a supracompetitive price pursuant to a contract because "[a] contract is a vehicle for determining at the time of contracting what should happen at some time thereafter." *Id.* at 69. However, the Court here is not dealing with an earlier contract for sale entered into between Humana and Celgene, and *US Airways* did not purport to overrule or abrogate *Berkey Photo*. Moreover, *US Airways* relied, in large part, on the Sixth Circuit's approach that an overt act cannot be a reaffirmation of a previous act. *Id.* at 68 (citing *DXS, Inc. v. Siemens Med. Sys., Inc.*, 100 F.3d 462, 467 (6th Cir. 1996); *Grand Rapids Plastics, Inc. v. Lakian*, 188 F.3d 401, 406 (6th Cir. 1999)). As just stated, the Third Circuit takes a different approach.

Fourth and finally, Celgene argues that the direct purchaser distinction only has teeth when the direct purchaser purchased a good or service within the limitations period for the first time. (Reply at 6). However, that limitation is nowhere in *Berkey Photo* or *Actelion*. And *Actelion* contains clearly inapposite language—that *each* sale of a drug at an unlawful supracompetitive price triggers a new statute of limitations period under the continuing violations doctrine.[5]

* * *

The Court finds the approach of the Second and Fourth Circuits persuasive and consistent with Supreme Court and Third Circuit precedent. For those reasons, the continuing violations doctrine saves Humana's claims, and the four-year statute of limitations does not bar suit.

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[5] *See also In re Mallinckrodt PLC*, No. 20-12522, 2021 WL 4876908, at *9 (Bankr. D. Del. Oct. 19, 2021) ("While the Debtors cite to several cases for the proposition that 'monopolistic' pricing is not, by itself, anticompetitive conduct, that is beside the point. The AICs have not alleged that the high price of Acthar is, in and of itself, the sole basis for the antitrust violation, but rather have alleged that the sales at the alleged supracompetitive price constitute overt acts in furtherance of a course of conduct that is, all together, a continuing violation of antitrust laws."); *id.* ("Here, by contrast, the Debtors continue to sell Acthar post-petition at what is alleged to be an anticompetitive price. If true, then the AICs' interests are repeatedly invaded with every sale and a continuing antitrust violation therefore exists.").

B. Sufficiency of the Complaint

The Court declines to consider the sufficiency of the Complaint on this briefing. While Celgene's motion to dismiss was pending, the Court received five other related cases that have been brought against Celgene: *United Healthcare Services, Inc. v. Celgene Corporation*, No. 20-18531 (D.N.J. Apr. 13, 2021); *BCBSM, Inc. et al. v. Celgene Corporation et al.*, No. 21-6668 (D.N.J. Mar. 25, 2021); *Blue Cross and Blue Shield Association v. Celgene Corporation et al.*, No. 21-10187 (D.N.J. Apr. 26, 2021); *Cigna Corporation v. Celgene Corporation et al.*, No. 21-11686 (D.N.J. May 24, 2021); and *MSP Recovery Claims, Series LLC et al. v. Celgene Corporation et al.*, No. 21-20451 (D.N.J. Dec. 29, 2021). The allegations in each case are similar, and Celgene intends to move to dismiss each complaint on similar grounds. Moreover, Humana has indicated that it intends, and the Court will so allow it, to amend the instant Complaint to add factual allegations.

Out of an interest in judicial economy and fairness to the other plaintiffs, the Court will require Celgene to re-move in this case and move in the other five cases—in one, consolidated brief. The other plaintiffs may then oppose Celgene's motions in one consolidated brief. This will allow the Court to efficiently sift through the allegations and consider the parties' arguments. It will also ensure that all plaintiffs in all cases have an opportunity to be heard before the Court renders a decision that might well be consequential to their cases.

Notably, it is appropriate to decide the underlying statute-of-limitations issue now. It is applicable to all pending matters, and although the other plaintiffs were not heard on it, no fairness concerns are present in deciding it now because the Court's holding runs in their favor.

IV. CONCLUSION

For the above stated reasons, the Court DENIES Celgene's motion to dismiss (D.E. No. 18). An appropriate Order will be entered.

Dated: April 27, 2022

Hon. Esther Salas, U.S.D.J.